

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

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IN RE BIOGEN '755 PATENT  
LITIGATION

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) Hon. Claire C. Cecchi  
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) Civil Action No. 10-2734  
) (CCC/JBC)  
) (consolidated)  
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**BIOGEN'S SUR-REPLY IN OPPOSITION OF BAYER HEALTHCARE  
PHARMACEUTICAL INC.'S MOTION TO STRIKE THE  
SUPPLEMENTAL REBUTTAL EXPERT REPORT OF PASTOR  
COUCEYRO**

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## **INTRODUCTION**

Biogen and Bayer have competing motions to strike reports from each other's experts, Dr. Gordon Moore for Bayer and Dr. Pastor Couceyro for Biogen. Biogen's position is that either both experts should be allowed to offer their opinions or neither should. In contrast, Bayer wants Dr. Moore to testify while Dr. Couceyro is prohibited from responding. The merits of the issues are teed up in the briefing.

Unfortunately, though, Bayer has abandoned the civility and respect that the parties and their counsel have always shown each other. The rhetoric in Bayer's opening brief in its motion to strike Dr. Couceyro's supplemental expert report was overheated. Biogen chose to respond not with similar angry rhetoric, but with facts. Bayer then used its reply brief to accuse Biogen of silently agreeing with Bayer's character attacks. Bayer thus opened its brief with a theatrical flourish from Walter Scott about deliberate deception, and proceeded to accuse Biogen of providing "repeated falsehoods and evasive answer[s] to the Court."

Biogen respectfully submits this sur-reply to respond to those attacks. It is a simple response: Biogen has not, at any time, set out to mislead this Court or counsel for Bayer.

## **ARGUMENT**

### **I. Biogen Did Not Delay Its Supplemental Report Until After Its Motion to Strike “Backfired”**

Bayer’s brief rests on two self-contradictory propositions: that Biogen willfully delayed conducting its own tests in order to strike the Moore Report, and that Biogen was conducting testing all along without telling the Court or Bayer. Thus, according to Bayer, Biogen both delayed conducting tests and rushed to conduct them. That makes no sense.

Here is what actually happened: Biogen moved to strike the Moore Report, and it sought to obtain tests of its own. The existence of such testing is attorney work product, as Bayer itself admits. (ECF No. 460 (Bayer’s Opposition to Biogen’s Motion to Strike the Moore Report) at 7-8.) Given that the first laboratory that Biogen hired—Charles River Laboratories—announced, after weeks of experimental design and preparation, that it could not complete the testing, Biogen had good cause to worry that it might not complete its testing. Once it was clear that the second laboratory, Lofstrand Laboratories, could complete its testing, Biogen disclosed the testing to Bayer, provided its testing protocol, and then provided its testing results.

**A. Biogen's Motion to Strike the Moore Report Rested on Far More Than the Possibility of Conducting Testing**

Bayer argues that Biogen moved to strike the Moore Report on a false pretense that Biogen could not conduct its own testing in time to respond to Dr. Moore. In truth, Biogen moved to strike the Moore Report for multiple reasons, only one of which was about testing. Thus, Biogen relied on Bayer's failure to disclose its "interferon alpha hybridization" invalidity theory in Bayer's invalidity contentions or interrogatory responses. Biogen noted that Bayer's theory raises new claim-construction disputes. Biogen argued that Bayer's late disclosure precluded Biogen from taking fact discovery regarding the status of "Clone 4" as prior art and regarding the tests that Marin Laboratories conducted for Bayer. And, finally, Biogen noted that there might not be enough time for Biogen to find a laboratory that conduct tests, determine the accuracy of the results, and disclose them timely during the expert discovery period. Biogen was explicit that even conducting and completing testing in time would not eliminate the prejudice Biogen suffered. (*See* ECF No. 457-1 at 13-14.)

**B. Biogen Did Not Have Test Results at Oral Argument**

Bayer is also inconsistent about when Biogen completed its testing. Thus, Bayer suggests that Biogen had finished its first set of tests before moving to strike the Moore Report (*see* Bayer Reply at 8) and that Biogen had final test results

before the November 22 oral argument (*see id.* at 7).

What Biogen had on November 22 was incomplete data from one of three experiments, without control data. Details matter here, and Bayer ignores them. One of Dr. Couceyro's (and Biogen's) criticisms of Dr. Moore's report is that Dr. Moore ran his experiment only once. Biogen designed its testing to be performed in triplicate, to ensure the robustness of the data. And in order to be sure that any data were reliable, Biogen tested not only the disputed Clone 4 but a control probe as well, called "Ampr." The test results tell the chronology: As of November 14, before the oral argument, Biogen had received the results of one half (Clone 4, but not the control Ampr data) of one of the three experiments, known as "Gel 1." The control results were not complete until December 9, however. *See* Supp. Balcof Decl., Ex. D and F (Appendices B and D to Couceyro Supplemental Rebuttal Report). Likewise, the Clone 4 probe results for the second and third replicates (called Gel 2 and Gel 3) are dated December 5, and the Ampr control results for Gel 2 and Gel 3 are dated December 9. *See* Supp. Balcof Decl. Ex. D and E (Appendices C and D to Couceyro Supplemental Rebuttal Report).

While the Clone 4 results from Gel 1 did support Biogen's arguments and undercut Dr. Moore's and Bayer's theory, and while Biogen had those preliminary data by November 22, the subsequent control experiments could have revealed the

partial data to be a false negative. Likewise, the subsequent data from Gel 2 or Gel 3 could have pointed in a different direction, or been inconclusive, or otherwise called into doubt the preliminary results. As of oral argument, all that Biogen knew was that the first of six headline results (one experimental result and one control result from each of three tests) looked good. That was hardly a basis from which to waive attorney work product and announce that testing was underway.

Bayer accuses counsel of Biogen of avoiding the Court's question, at the November 22 oral argument, of "Are you still interested in looking for another lab?" (ECF No. 482-12 at 126.) Biogen's answer, informed by the Court's already having stated that it was not inclined to strike the Moore Report, was to reiterate Biogen's interest in finding "some series of steps that we can do that we think puts us on an equal footing here, or as far as possible, with Bayer." (*Id.*) Counsel continued that Biogen would think about its options, make a proposal to Bayer, and then come to the Court (which is exactly what Biogen thereafter did): "And I mean, one way forward would be for us to think about that and then come back in the first instance I suspect to counsel for Bayer and ultimately to the Court and say, how about if we do this." (*Id.*)

Bayer apparently thinks Biogen should have said, "We are already moving forward with another lab, Your Honor." Biogen respectfully disagrees. To do so

would have waived the work-product protection, and with only partial results in hand, without any control data yet available, with only one of three experiments even partially complete, and with the prior laboratory having unceremoniously quit, doing so would have been completely inappropriate. Bayer identifies no false statement, because there was none. It identifies no material omission, because there was none. Biogen's response left open that Biogen would propose a path forward that might or might not involve testing with an additional laboratory, and Biogen then followed exactly the path it laid out.

**C. Biogen Did Not Mislead the Court in Its December 13 Letter**

Bayer next focuses on Biogen's December 13 letter in which Biogen proposed serving the Supplemental Couceyro Report, and specifically on this passage:

[I]t bears noting that circumstances have changed since Biogen filed its Motion to Strike. Then, it seemed unlikely that Biogen could cure the prejudice caused by Bayer's untimely disclosure because Biogen could not find a laboratory to conduct the requisite Clone 4 experiments. . . . Subsequently, however, Biogen was able to retain the services of a properly certified laboratory to perform the experiments on an expedited basis.

(ECF No. 479 at 2.)

There is nothing misleading in this paragraph. Circumstances had changed since Biogen filed its Motion to Strike. Chief among them, the Court had expressed a disinclination to grant the motion. (*See* 11/22/2016 Tr. at 122:23-



123:5.) Moreover, Biogen's concern that it had no time to take discovery regarding the origin of Clone 4 and whether Clone 4 was in the prior art had been mooted in part by Bayer's statement at the November 22 hearing that "Clone 4 is not in the prior art." (11/22/2016 Tr. at 110:9-15.) And as of December 9, when Lofstrand Laboratories completed the "Ampr" control data for each of the three experiments, Biogen had in its possession empirical data from a well-designed and well-controlled experiment demonstrating that Clone 4 does not hybridize to HFIF3 or HFIF6 under the conditions of the '755 patent.

As for the second sentence of the paragraph, it is true too. When Biogen moved to strike, it did seem unlikely that Biogen could find a laboratory to conduct the requisite Clone 4 experiments. Before quitting the project, Charles River Laboratories had estimated that it would take them several months to complete the experiments. Biogen had retained Lofstrand Laboratories before it filed its motion to strike, but knew from its prior experience with Charles River that merely retaining a laboratory is only a small part of the process. Samples of the DNA to be tested were being prepared and would be delivered to Lofstrand two days later. Whether Lofstrand would actually be able to conduct the experiments and how long that might take were still unknown at that point.

The use of "Subsequently" in the third sentence, however, was imprecise,

and thus an error. The sentence is correct to the extent that it says that “subsequent” to the motion to compel, Biogen was able to confirm that a properly certified laboratory could conduct the tests. Biogen did not, however, “retain” Lofstrand subsequent to filing its motion to compel; Biogen retained Lofstrand before filing that motion. The “Subsequently” sweeps too broadly.

The error is of no substantive consequence, however. That is, nothing would have been different in any way had Biogen’s December 13 letter said “Subsequently, however, Biogen was able to confirm that a properly certified laboratory can perform the experiments on an expedited basis.” The point of Biogen’s letter was to confirm that Biogen had completed its testing, and to propose the service of the Supplemental Couceyro Report and thus the mooted of Biogen’s Motion to Strike. Biogen has since served that report. If Dr. Moore is to be permitted to rely on the testing in his report, Dr. Couceyro should be permitted to rely on the testing Biogen did in response.<sup>1</sup>

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<sup>1</sup> There is another error in Biogen’s December 13 letter, which Biogen noticed in writing this sur-reply brief. The letter says that Charles River Laboratories was unable to proceed because of the use of radioactive labeling materials in the proposed tests. In fact, Charles River could not conduct the testing because of concerns about its Good Laboratory Practices certifications. Biogen’s counsel actually explained this (correctly) at the November 22 hearing. (11/22/2016 Tr. at 124:3-15.) This error in the December 13 letter is also inconsequential here but, having discovered it, Biogen wishes to bring it to the Court’s attention.

## II. Subsequent Events Demonstrate Bayer's Lack of Prejudice

Some of the substantive parts of Bayer's Reply Brief also warrant a brief response:

- The reason that Biogen's tests do not perfectly mirror Dr. Moore's tests is that Dr. Moore's experimental design was deeply flawed. Biogen has attempted through its testing to answer the question Bayer and Dr. Moore pose: Does "Clone 4" hybridize to HFIF3 or HFIF6 under the conditions set forth in the '755 patent? That the experts reach different opinions, and that they use different test methods, is grist for cross-examination.
- Likewise, Lofstrand Laboratories used less DNA in its tests than Dr. Moore used because Dr. Moore did his test improperly. Bayer's further criticism—that Lofstrand used "so little DNA is that it makes signals less likely to be detected," Reply at 12—is disproved by the positive control data in Lofstrand's experiments. Bayer can explore this on cross, too.
- Bayer complains that it is prejudiced by Dr. Couceyro's Supplemental Rebuttal Report because it doesn't know the DNA sequence of the test samples and that it will take 12 weeks to ascertain the sequences of the samples. *See* Reply at 14. Biogen provided Dr. Couceyro's DNA sequencing data for both HFIF3 and HFIF6 to Bayer during fact discovery. Lofstrand Laboratories is also re-sequencing the HFIF3 and HFIF6 DNA. Lofstrand estimates it will take them a week at which point Biogen will provide Lofstrand's sequence data as well.

So, too, do some events that occurred after Bayer filed its sur-reply. Last week, Bayer's principal invalidity expert, Dr. Jeffrey Ravetch, was deposed. He came prepared to offer at least five substantive criticisms of Dr. Couceyro's Supplemental Report. Likewise, last week Bayer deposed one of Biogen's principal validity experts, Dr. Michael Green. Its counsel showed Dr. Green one of

the experimental results from Lofstrand Laboratories, and obtained his opinions about them. On Friday of last week, Biogen provided Bayer's counsel with information it had requested from Lofstrand.

Notably, throughout all of this, Bayer's counsel approached Biogen's counsel with the civility and professionalism with which the parties had been treating each other since this case was filed in 2010. Biogen hopes, then, that Bayer's reply brief was an aberration.

### **CONCLUSION**

The Court asked the parties to find a way to moot Biogen's Motion to Strike the Moore Report. Biogen thinks it has done so, and that the right approach is for Bayer to take Dr. Couceyro's deposition about his Supplemental Expert Report and for the case to move forward.

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Chatham, New Jersey

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